Rejection under 35 U.S.C. § 112

Claims 1-8 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification ins such a way as to reasonably convey that the inventor had possession of the claimed invention. Specifically, the examiner has stated that the application does not contain any teaching for the claimed feature, "sustained release of substances over a period of time." The Collins English Dictionary (Updated 3rd Edition, HarperCollins Publishers, 1994, pg. 1554) defines the term "sustain" to mean *"to maintain or prolong."*

The present invention relates to a substance delivery system for use in animal body cavities. Such delivery systems are extensively used in controlled breeding and reproductive management, as described in the background art section of the present specification. Such devices are required to be retained within the body cavity for the slow release of drugs over a period of time. *See* page 1, lines 14-15.

An example of such reproductive management is described on page 2, lines 19-24 of the present specification.

> *"Exogenous progesterone is delivered to cows to inhibit follicles maturation as a means of synchronising oestrus. When the treatment is removed progesterone levels fall and the animal cycle in a controlled manner. If however the progesterone blood levels during treatment fall below critical levels, oestrus synchronisation may still occur but follicle integrity may be compromised thereby reducing conception rates and fertility."*

This condition is stated to highlight "*the necessity to maintain adequate progesterone dose [during treatment] using an efficient drug delivery system.*" *See* page 2, line 24 to page 3, line 1. It is submitted that any skilled addressee thus would

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understand the requirement for maintaining an adequate release of a dose over a prolonged period of time and that such release could also be described as "sustained."

Further, in preferred embodiments of the present invention the material from which the substance is dispensed is biomedical silicone elastomer. *See* page 10, lines 7-8. The use of the substance dispenser is stated to *"provide the ability to replenish treatments or applications, and/or apply them for sustained periods by replacing the dispenser, or adding a supplementary dispenser." See* page 10, lines 16-18.

A further example of the benefits of the dispenser application of the present invention is described on page 11, lines 1-6 which states *"in the intravaginal delivery of progesterone in cattle, ...progesterone is impregnated into a silicone matrix requiring a sustained dose of approximately 2ng/ml of exogenous progesterone in the blood."*

The applicant also discloses numerous means for providing sustained release of drugs over a period of time, including biodegradable coatings, electronically controlled pumps or cavities to allow such sustained or prolonged release. *See* page 11, lines 7-12.

The background section of the specification also details how treatment times may vary, for example one treatment may require six days of drug delivery, whereas another treatment may require ten days of drug delivery. *See* page 3, lines 6-11. It is stated that it would be desirable to have a drug delivery device that delivers the drug in a sufficient quantity over the treatment period. *See* page 3, lines 12-16.

The specification also describes the recognition of the applicant for controlled drug release. *See* page 4, lines 13-20; page 11, lines 7-12. Also, the ability of the present invention to regulate the device surface area to influence those levels and to

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regulate the dose profile through matrix thickness enables specific dose formulations to be delivered. *See* page 8, lines 3-5.

The disclosure by the Applicant for maintaining a controlled, prolonged release of drugs over a period of time is intended to teach the "sustained release" of substances. Accordingly, Applicant respectfully requests that the Examiner withdraw the objection.

Rejection under 35 U.S.C. § 102(b)

Claims 1-8 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,818,911 to Fourneir. Applicant respectfully traverses this rejection. Claim 1 is directed to a substance delivery device adapted for insertion into a body cavity, the substance delivery device including, *inter alia*, a substance dispenser including a plurality of finger means for allowing sustained release of substances over a period of time. Fournier does not anticipate a substance delivery device including a plurality of finger means for allowing sustained release of substances over a period of time.

The substance delivery device is designed to be retained within the body cavity for the sustained release of drugs over a period of time. As set forth above, treatment times may vary. *See* page 3, lines 6-11. Applicant discloses numerous means for providing sustained release of drugs over a period of time. For example, biodegradable coating, electronically controlled pump, or cavities may allow the sustained release of drugs. *See* page 11, lines 7-12. In addition, the sustained release of drugs may be provided by impregnated gills. The thickness and number of gills control the duration and profile of the dose. *See* page 11, lines 20-24.

Fournier, in contrast, is designed to be used as an applicator swab. The applicator swab is used to apply a single dose of a medication composition to an

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internal body surface. *See* col. 1, lines 44-47. For these reasons, Fournier does not anticipate claim 1 and the rejection should be withdrawn. Moreover, the Examiner stated in responding to Applicant's October 5 Amendment that "[i]n response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., the sustained release of drugs over a period of time) is not recited in the rejected claims." Applicant has amended claim 1 to recite that limitation and therefore claim 1 is allowable for at least that reason.

Claims 2-8 depend from and add additional feataures to independent claim 1. Accordingly, these claims are allowable for at least the reasons that claim 1 is allowable. Applicants respectfully request that the Examiner withdraw the rejection.

Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests the timely allowance of the pending claims. Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: June 2, 2003

By: _____
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